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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,788	10/17/2003	Shamci Monajembashi	SHA-001	9873
3897	7590	08/18/2006	EXAMINER	
SCHNECK & SCHNECK P.O. BOX 2-E SAN JOSE, CA 95109-0005			WHALEY, PABLO S	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,788

Applicant(s)

MONAJEMBASHI, SHAMCI

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/21/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

APPLICANT'S ELECTION

Applicant's election traverse of Group II (Claims 16-26, 28, and 29) and Specie B (ii) (beams coupled via a system of lenses) in the reply filed on 06/19/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-15 and 27 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim.

CLAIMS UNDER EXAMINATION

Claims herein under examination are Claims 16-26, 28, and 29 as they read on the elected species. An action on the merits follows.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement filed 05/21/2004 has been considered in full.

FOREIGN PRIORITY

Papers filed 01/12/2004 for foreign priority are acceptable.

DRAWINGS

The drawings filed 10/17/2003 are accepted.

LACK OF UTILITY

Claims 16-26, 28, and 29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well-established utility.

In the instant case, the claimed invention is not supported by a well-established utility. The instant claims generally recite a method for producing optically induced mechanical forces on a target object, with no limitation as to the type of object. If the intended utility of this invention is for the mechanical deformation of cells, as stated in the specification [p.1], then the instant claims are not commensurate in scope with the stated utility. Furthermore, the specification discloses several general disciplines where the instant invention may be "useful" for diagnosis of disease and in epithelial cell research [p. 10-11]. However, the disclosed utilities are not specific to the instant claims. For these reasons, the claimed subject matter does not have a specific, substantial, and credible utility.

Claims 16-26, 28, and 29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

CLAIM REJECTIONS - 35 USC §112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16-26, 28, and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing optically induced mechanical forces on target cells, does not reasonably provide enablement for producing optically induced mechanical forces on target objects. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below which leads to the determination that the above claim lacks enablement due to undue experimentation being required to make and use the invention.

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In the instant case, the claimed subject matter lacks enablement for the following reasons:

The instant claims are generally directed to a method for producing optically induced mechanical forces on a target object. Given the nature of the invention, this requires an actual step of producing an optically induced mechanical forces [See USC 112 2nd rejection below]. However, there is no such limitation in the instant claims. It is noted that the specification discloses the use of optical tweezers (i.e. lasers) for producing optically induced mechanical forces, however the claims do not recite such limitations. [Wands factors (2), (4), (8)].

Instant claim 18 recites the limitation "linking includes fixing." The specification discloses "fixed cells" [p.6, lines 5-6] and methods by which objects stay "fixed" [p.10, lines 10-15] but does not define or fully and completely describe "fixing" [See USC 112 2nd rejection below]. Therefore it is unclear how the applicant's are "fixing" said objects. The specification discloses methods for coating cells to facilitate adhesion [p.7]. However the instant claims do not recite such limitations. [Wands factors (2), (4), (8)].

Instant claim 20 recites the limitation "attaching...objects." As the specification does not define or fully and completely describe "attaching", it is unclear how applicant are attaching said objects [See USC 112 2nd rejection below]. The specification discloses methods for coating cells to facilitate adhesion [p.7]. However the instant claims do not recite such limitations. [Wands factors (2), (4), (8)].

Methods for measuring elastic coefficients of human erythrocytes using optical tweezers and microbeads are well known in the art (Biophysical Journal, 1999, Vol. 76, p.1145-1151). Despite the high level of skill in the art, as the steps of the instant claims are not limited to cells and lack sufficient guidance as to the methods for attaching and fixing objects, as set forth above, one skilled in the art would not know how to produce optically induced mechanical forces

on a target object, therefore it would require undue experimentation by one of skill in the art to predictably practice the instantly claimed invention. [Wands factors (1), (2), (6), (7)].

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites a method for “producing optically induced mechanical forces on a target object” in the preamble. However, there are no steps directed to producing an optically induced forces recited in claim 16. Therefore it is unclear in what way the instant claims achieve the purpose of the preamble. If applicant intends for “manipulation” (line 9) to equate to “producing...forces”, this should be clearly stated in the claim. Clarification is requested.

Claim 16 recites the limitation “providing target objects.” It is unclear whether said “providing” is a physical method step, a limitation of instant method, or otherwise. Furthermore, it is unclear whether the said target objects are cells, beads, or something else. If applicant’s intend for said target objects to be something other than cells or beads, it is unclear in what way the auxiliary objects, which may include heamoglobin or derivatives, relate to the target objects. Clarification is requested.

Claims 16 and 22 recite the limitation “linking.” As the specification does not define or fully and completely describe “linking” for carrying out the intended function, it is unclear in what

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way objects are linked (i.e. physically connected, chemically bonded, etc.). Clarification is requested.

Claim 18 recites the limitation "linking includes fixing." As the specification discloses "fixed cells" [p.6, lines 5-6] and methods by which objects stay "fixed" [p.10, lines 10-15] but does not define or fully and completely describe "fixing", it is unclear as to the intended meaning of fixing in this context. Clarification is requested. For purposes of examination, fixing is hereby interpreted as "binding."

Claim 20 recites the limitation "attaching...objects." As the specification does not define or fully and completely describe "attaching", it is unclear in what way attaching relates to the said objects. Clarification is requested. For purposes of examination, attaching is hereby interpreted as "binding."

Claim 22 recites the limitation "manipulated by said coupled beam passage and laser beam toward said focus" (line 4). It is unclear whether the beam passage, the laser beam, or both is required for said manipulation. Furthermore, it is unclear whether the beam, the passage of the beam, the object, or some combination thereof is moving "toward said focus." Clarification is requested.

Claim 22 recites the limitation "object is manipulated....., manipulating...." . It is unclear whether the said "manipulating" step is a result of the object being manipulated, a further limitation of the method, or otherwise. Clarification is requested.

It is noted that for purposes of prior art, the Examiner has examined the claims using the broadest, reasonable interpretation. Because the instant claims are broad with respect to targeting objects, linking, and applying, the Examiner has applied the following art.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 18-26, and 28 are rejected under 35 U.S.C. 102 (b) as being anticipated by Henon et al. (Biophysical Journal, 1999, Vol. 76, p.1145-1151).

Henon et al. teach a method and system for measuring elastic coefficients of human erythrocytes using optical tweezers [Abstract]. More specifically, Henon et al. teach the following aspects of the instant invention:

- Erythrocytes (i.e. auxiliary objects) bound to silica beads (i.e. target objects) [Abstract], as in instant claims 16, 18, 20, and 23.
- Optical tweezers comprising multiple laser beams used to apply force to erythrocytes bound to silica beads [Abstract and Fig. 1], as in instant claims 16, 19, 24, and 25.

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- Optical tweezer system comprising lenses, a microscope, focused laser beams coupled into beam passage via lenses, and target objects [Fig. 1], as required by Species B (ii) and as in instant claims 21 and 28.
- Laser beam is focused at an observation point [p.1146, Col. 1, ¶ 1], which equates to a "focus" as in instant claims 21 and 22.
- Laser beam with wavelength of 1.064 micrometers [Fig. 1], which is a teaching for longwave as disclosed in the specification [p.8] and as in instant claim 26.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17 and 29 are rejected under 35 U.S.C. 103(a) as being made obvious by Henon et al. (Biophysical Journal, 1999, Vol. 76, p.1145-1151), as applied to claims 16, 18-26, and 28, above, in view of Visscher et al. (Cytometry, 1993, Vol. 14, p.105-114).

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Henon et al. teach a method and system for measuring elastic coefficients of human erythrocytes using optical tweezers [Abstract], as set forth above.

Henon et al. do not specifically teach a coating objects with substances, as in instant claim 17, or confocal laser scanning microscope system, as in instant claim 29. However, Henon et al. suggest coating RBCs with buffers to improve cell geometry [p.1145, Materials and Methods] and multiple trapping experiments applied to red blood cells [p.1145, Col. 1, ¶ 2].

Visscher et al. teach the use of a confocal scanning laser microscope for the micromanipulation of bacterial cells using multiple optical traps [Abstract], as in instant claim 29. Visscher et al. also teach the coating of beads with specific cell binding antibodies to improve trapping [p.113, Col. 2, ¶ 1], which implicitly change surface charge, as in instant claim 17.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to combine the confocal scanning laser system with the optical tweezer method and system of Henon et al., where the motivation would have been use a fast multiple trap system enabling the orientation of irregular shaped structures [Visscher et al., Abstract], resulting in the practice of the instant claimed invention. One of skill in the art would have had a reasonable expectation of successfully using the confocal scanning laser system with the optical tweezer method and system of Henon et al. as both teach bead-based systems for optical manipulation of cells using single and multiple traps [Henon et al., p.1145, Col. 1, ¶ 1].

CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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8/14/06